NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, **Plaintiff,** **v.** **ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS, INC., *et al*.,** **Defendants.**	**Civil Action No. 07-3770 (DMC)** **OPINION**

FALK, U.S.M.J.

Before the Court is Plaintiff's motion *in limine* to permit Steven M. Paul, M.D. ("Dr. Paul") to testify as a fact witness at trial. [CM/ECF No. 575.] Defendants have opposed the motion. [CM/ECF No. 592.] The Court heard oral argument on May 5, 2010, and placed an oral opinion on the record to expedite disposition of the motion. This written opinion supplements the oral opinion. See L. Civ. R. 52.1.[1] For the reasons set forth below, and for those previously stated on the record, Dr. Paul will not be excluded from testifying at trial, provided he is made immediately available for a deposition for which Plaintiff will bear all costs and expenses.

[1] A court may "render an oral opinion or decision or merely an order and then supplement it with a written opinion. Technically, the written opinion is filed pursuant to L. Civ. R. 52.1." Allyn Z. Lite, New Jersey Federal Practice Rules, comment 2 to L. Civ. R. 52.1 at 209 (2010 ed.).

BACKGROUND

A. Patent-In-Suit

This is a patent infringement action brought by Plaintiff, Eli Lilly & Company ("Plaintiff" or "Lilly"), under the Hatch-Waxman Act. Lilly is the owner of United States Patent No. 5,658,590 ("the '590 patent"). The '590 patent covers a method of using the drug atomoxetine to treat attention-deficit hyperactivity disorder ("ADHD"). Lilly manufactures its atomoxetine drug under the trade name Strattera®. Defendants Apotex, Inc., Aurbindo, Sun Pharmaceuticals, Sandoz, Inc., and Mylan Pharmaceuticals (collectively "Defendants") filed Abbreviated New Drug Applications with the FDA to market and sell generic versions of Strattera®. The case is scheduled for a bench trial before District Judge Cavanaugh beginning on May 18, 2010, and the primary issues are whether the '590 patent is invalid as obvious, invalid for a lack of enablement/utility, or unenforceable.

B. The Final-Pretrial Conference

On April 19, 2010, the Court conducted a final pretrial conference. In the proposed final pretrial order provided to the Court that day, the parties did not identify their contemplated motions *in limine*, which is contrary to Judge Cavanaugh's pretrial requirements. (Transcript of April 19, 2010 Final Pretrial Conference ("Tr.") at 6:15-17.) The Undersigned inquired whether the parties contemplated filing any *in limine* motions that involved routine discovery issues -- *e.g.*, failure to identify witnesses or disclose documents during discovery. (Tr. at 6:17-20.) In response, the parties informed the Court, for the first time, that Lilly intended to call Dr. Steven Paul to testify as a fact witness at trial, even though Dr. Paul was not listed in Lilly's initial disclosures and was first identified as a Lilly fact witness on April 5, 2010, during joint preparation of the final pretrial order.

(Tr. 6:20-10:22; 12:13-19.) Lilly stated that Dr. Paul was Vice President and then President of Lilly Research Laboratories and that he has factual knowledge relating to the development of the drug-in-suit. (Tr. 10:24-11:3; 11:6-11.) Lilly further stated that Dr. Paul is simply a substitute witness, replacing another doctor, August M. Watanabe, M.D., who died last year. (Tr. 10:14-22; 11:6-25.) Dr. Watanabe was the former President of Lilly's research arm; Dr. Paul was his successor. Lilly claimed that Dr. Paul's testimony would be the same testimony that Dr. Watanabe would have provided at trial. (Tr. 11:12-14; 24:1-11.)

Defendants, claiming prejudice and surprise, sought to exclude Dr. Paul from testifying at trial. (Tr. 12:13-19.) Lilly countered that Dr. Paul had been adequately disclosed during depositions taken in the course of discovery and offered to make him available for a deposition on short notice. Lilly was directed to immediately file a motion *in limine* requesting that Dr. Paul be permitted to testify at trial. (Tr. 20:23-21:1.) Lilly was also directed to include with any *in limine* motion a detailed proffer of Dr. Paul's proposed testimony. (Tr. 26:4-17.)

Lilly's motion was filed on April 26, 2010; it contains a 5 page general proffer of Dr. Paul's testimony. Defendants' opposition was filed on April 30, 2010. On May 5, 2010, oral argument was held. Hundreds of pages of new exhibits and demonstrative slides were submitted to the Court at the oral argument.

C. The Parties' Arguments

Lilly argues that Dr. Paul should not be excluded from trial because he was identified as a person with knowledge during four depositions, all of which occurred prior to the close of fact discovery -- which it claims satisfies Rule 26's disclosure requirements. (Pl.'s Br. 4-8.) Lilly claims that Dr. Paul will testify about the steps and procedures Lilly took to develop atomoxetine, and that

those steps and procedures showed that atomoxetine was proving to be, and indeed was, a useful drug. Lilly argues that it did not realize that Dr. Paul was a necessary witness until after Judge Cavanaugh resolved a motion for summary judgment and a motion for reconsideration that effectively rejected Lilly's other evidence on the enablement/utility issue. Lilly admits that it did not name Dr. Paul in its initial disclosures or provide his name in response to discovery requests, but claims that he was referenced during deposition testimony of other fact witnesses. In the event Dr. Paul was not adequately disclosed, Lilly argues that a balancing of the relevant factors shows that any prejudice can be cured by deposing Dr. Paul prior to trial.

Defendants strenuously oppose Dr. Paul's participation at trial for various procedural and substantive evidentiary reasons. Defendants argue that Lilly failed to disclose Dr. Paul in its initial disclosures; in responses to pointed and unambiguous interrogatories; and in response to a request for a 30(b)(6) deposition served on Lilly during discovery. (Defs.' Br. 9-16.) They further argue that Lilly's disclosure of Dr. Paul occurred ten months after Dr. Watanabe's death, which undercuts the notion that he is simply a replacement witness. Defendants contend that the "disclosure" of Dr. Paul in various depositions was vague and failed to convey the nature and substance of his alleged knowledge. (Id.) Defendants also contend that Lilly's failure to disclose Dr. Paul and his knowledge until the eve of trial results in substantial and incurable prejudice. (Defs.' Br. 19-21.) They argue that Lilly has essentially changed its legal contentions on the eve of trial and seeks to "sandbag" them by supporting its new legal theories with a previously undisclosed witness. Finally, Defendants argue that nearly all of Dr. Paul's testimony is substantively barred by the Court's prior decisions and would amount to inadmissible expert and lay opinion testimony, hearsay evidence, rank speculation, and would otherwise be inadmissible at trial. (Defs.' Br. 17-25.)

DISCUSSION

A. Legal Standard

1. Disclosures & Supplementing Discovery Responses

Federal Rule of Civil Procedure 26(a)(1)(A) requires the disclosure of, among other things, the name, address and telephone number of each individual possessing relevant information, along with the subject of that information, that the disclosing party intends to use to support its claims or defenses. Id.

Rule 26 disclosures are meant to provide the opposing party with "information as to the identification and location of persons with knowledge so that they can be contacted in connection with the litigation . . . for being interviewed, for being deposed, or for providing background information." Bilrite Corp. v. World Road Markings, Inc., 202 F.R.D. 359, 362 (D. Mass. 2001); see also Fitz, Inc. v. Ralph Wilson Plastics, Co., 174 F.R.D. 587, 589 (D.N.J. 1997). The fundamental purpose of early disclosures is to accelerate the exchange of information needed to assess settlement, assist the parties in organizing and prioritizing their discovery, and prepare the case for trial. See, e.g., Advisory Committee Note to Rule 26(e) (1993)[2]; City & County of San Francisco v. TutorSaliba Corp., 218 F.R.D. 219, 221 (N.D. Cal. 2003).

A party has a continuing duty to keep its disclosures and discovery responses current. Rule 26(e)(1)(A) imposes an obligation on a party to update its Rule 26(a) disclosures and discovery responses during the course of a litigation as follows:

> A party who has made a disclosure under Rule 26(a) — or who has

[2] In interpreting the Federal Rules, the Advisory Committee Notes "are a very important source of information and should be given considerable weight." Reed v. Binder, 165 F.R.D. 424, 427 (D.N.J. 1996) (citing Miss. Publ'g Corp. v. Murphee, 326 U.S. 438, 444 (1946)).

> responded to an interrogatory, request for production, or request for admission — must supplement or correct its disclosure or response:
>
> (A) in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing . . . .

Fed. R. Civ. P. 26(e)(1)(A).

A party is continually required to supplement or correct its initial disclosures (as well as any discovery responses) if their disclosures are in any way "incomplete or incorrect." Fed. R. Civ. P. 26(e). In the event disclosures become incomplete or incorrect, the party *must* correct its disclosures -- formally -- unless the corrective information has "otherwise been made known." Fed. R. Civ. P. 26(e). The obligation to update initial disclosures is meant to ensure that the playing field remains level, narrow the relevant issues, and avoid "undue prejudice and surprise" to the opposing party. Reed v. Iowa Repair & Marine Co., 16 F.3d 82, 85 (5th Cir. 1994); see Poulin v. Greer, 18 F.3d 979, 984 (1st Cir. 1994); Am. Stock Exchange, LLC v. Mopex, Inc., 215 F.R.D. 87, 93 (S.D.N.Y. 2002).

A majority of courts, the leading treatises, and the Advisory Committee Note to Rule 26 agree that an individual's existence or knowledge can "otherwise be made known," and thus be sufficiently disclosed for Rule 26 purposes, through deposition testimony. See, e.g., In re Jacoby Airplane Crash Litig., No. 99-6073, 2007 WL 559801, at **8-10 (D.N.J. Feb. 14, 2007); Weiland v. Linear Constr., Ltd., No. 00-6172, 2002 WL 31307622, at *2 (N.D. Ill. Oct. 15, 2002); 8A Charles A. Wright, et al., Federal Practice and Procedure § 2049.1 ("[T]here is no need as a matter of form to submit a supplemental disclosure to include information already revealed by a witness

in a deposition or otherwise through formal discovery); 6 James WM. Moore, et al., Moore's Federal Practice § 26.131[1] ("The duty to supplement generally does not extend to disclosures made as part of deposition testimony."); Advisory Committee Note to Rule 26(e) (1993) ("There is, however, no obligation to provide supplemental or corrective information that has been otherwise made known to the parties in writing or during the discovery process, as when a witness not previously disclosed is identified during the taking of a deposition.").

However, the mere mention of an individual's identity during the course of a deposition is not sufficient. See, e.g., Muldrow v. Brooks, 34 Fed. Appx. 854, 854 (3d Cir. 2002); cf. Ty, Inc. v. Publications, Int'l, Inc., No. 99-5565, 2004 WL 421984, at *4 (N.D. Ill. Feb. 17, 2004) ("However, merely because the names of these witnesses appeared, among hundreds of other names, somewhere in the thousands of pages of documents produced . . . . does not mean that [the plaintiff] should have anticipated that [the defendant] would call these individuals as trial witnesses and deposed them accordingly."). Rather, as former District Judge Lifland explained in a Hatch-Waxman patent case, in order to qualify under the "otherwise been made known" language, the "*alleged disclosure must be clear and unambiguous*." Pfizer v. Teva, No. 04-754, 2006 WL 2938723, at *3 (D.N.J. Oct. 13, 2006) (emphasis added); see also e.g., Zoltek Corp. v. United States, 71 Fed. Cl. 160, 168 (Ct. Cl. 2006) ("Although the 'otherwise made known' standard of [Rule 26] may be met where disclosure of the information in question is clear and unambiguous, the standard is not satisfied where the disclosure is not sufficiently clear."); Gutierrez v. AT&T Broadband, LLC, 382 F.3d 725, 732-33 (7th Cir. 2004). Alleged "disclosures" during discovery that are not facially apparent and require the drawing of further "inferences" are insufficient to meet the requirements of Rule 26. Pfizer, 2006 WL 2938723, at *3. The determination of whether an

alleged disclosure satisfies the "otherwise made known" requirement is ultimately fact and case specific. See Fast Food Gourmet, Inc. v. Little Lady's Food, Inc., No. 05-6022, 2007 WL 3052944, at *4 (N.D. Ill. Oct. 18, 2007).

2. Failure to Disclose/Supplement & Exclusion Under Rule 37

In the event a party fails to disclose information pursuant to Rule 26(a), or supplement a discovery response or disclosure in accordance with Rule 26(e), Federal Rule of Civil Procedure 37 provides that "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. 37(c)(1).

Rule 37 provides a strong inducement for disclosure of Rule 26(a) material. Newman v. GHS Osteopathic, Inc., 60 F.3d 153, 156 (3d Cir. 1995). "Failure to comply with Rule 26(a) precludes a party from using any information or witness not disclosed." Harlow v. Eli Lilly & Co., No. 94-4840, 1995 WL 319728, at *1 (N.D. Ill. May 25, 1995).

However, exclusion under Rule 37 is not automatic. See Newman, 60 F.3d at 156 ("[Rule 37] does not leave the court without discretion."). The Third Circuit has identified four factors to consider when evaluating whether a failure to disclose or supplement warrants exclusion of evidence: "(1) the prejudice or surprise of the party against whom the excluded evidence would have been admitted; (2) the ability of the party to cure the prejudice; (3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case or other cases in the court; and (4) bad faith or willfulness in failing to comply with a court order or discovery obligation." Nicholas v. Pa. State Univ., 227 F.3d 133, 148 (3d Cir. 2000).

Exclusion of evidence is an "extreme" sanction, not normally imposed absent a showing of

willful deception or "flagrant disregard of a court order by the proponent of the evidence." Konstantopoulous v. Westvaco Corp., 112 F.3d 710, 719 (3d Cir. 1997) (quoting Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 905 (3d Cir. 1977)); Quinn v. Consol. Frieghtways Corp of Del., 283 F.3d 572, 577 (3d Cir. 2002) (finding that district court abused its discretion in excluding critical evidence where there was no indication that the plaintiff acted in bad faith).

The availability of alternative sanctions and the importance of the potentially excluded evidence should be considered prior to prohibiting the use of a witness or evidence at trial. See Konstantopoulous, 112 F.3d at 719. Indeed,"[t]he use of an undisclosed witness should seldom be barred unless bad faith was involved." Bergfeld v. Unimin Corp., 319 F.3d 350, 355 (8th Cir. 2003) (emphasis added); Mawby v. United States, 999 F.2d 1252, 1254 (8th Cir. 1993). Ultimately, whether to exclude evidence is left to the trial court's discretion. See, e.g., Fed. R. Civ. P. 37(c)(1)(A)-(C); Newman, 60 F.3d at 156 ("the imposition of sanctions under Rule 37 is a matter within the discretion of the trial court").

B. Chronology

The Court includes the following chronology of certain relevant dates to place this motion in context. The Court has relied liberally upon the parties' submissions in doing so.

- ***August 9, 2007***: Lilly filed its complaint alleging patent infringement.
- ***November 2, 2007***: Lilly served its Rule 26(a) initial disclosures, identifying four individuals. Dr. Paul was not identified.
- ***January 18, 2008***: Lilly served its responses to Defendants' interrogatories. No information regarding IND 46,806[3] is provided. Defendant Mylan Pharmaceutical's

[3] IND is an acronym for Investigational New Drug Application. See 21 C.F.R. §312.3(b). Before a drug manufacturer can proceed with clinical trials, an IND must be submitted to the

interrogatories specifically request that Lilly identify all animal and human clinical studies, including "Phase I trials, Phase II trials, and Phase III trials," and identify for each "how each study or trial was conducted." (Lilly's Responses to Mylan's Interrogatories, dated January 18, 2008, attached to the Declaration of Melissa Steedle Bogad, Esq., ("Bogad Decl.") at Ex. C.) Dr. Paul is not disclosed.

- ***August 28, 2008***: Lilly supplemented its initial disclosures, identifying four additional individuals. Dr. Paul was again not identified.

- ***September 16, 2008***: Lilly served its response to Defendants' Rule 30(b)(6) notice requesting identification of an individual competent to testify regarding the preparation and filing of IND 46,806. (Bogad Decl., Ex. F.) Lilly did not identify Dr. Paul. Lilly claims that the IND is not likely to lead to the discovery of admissible evidence. It also represented that it had no responsive information in its possession, custody or control; Lilly instead states that it is aware of the testimony of Dr. Thomas Spencer, a physician at Massachusetts General Hospital, concerning the IND but is otherwise not in possession of responsive information.

- ***October 1, 2008***: Defendants conducted the deposition of Dr. Watanabe.

- ***October 3, 2008***: Lilly's Director of Product Development, Martin Hynes, M.D., testified that he had not seen IND 46,806 and had no knowledge of whether Lilly maintained a copy of this IND.

- ***October 10, 2008***: Fact discovery closed.

- *November 24,* ***2008***: Lilly responds to Defendants' contention interrogatories. Lilly does not mention IND 46,806 in response to Defendants' contention interrogatories regarding Defendants' lack of enablement/non-utility defense. It also does not mention a legal theory of utility/enablement based upon the testimony of any fact witness such as Dr. Paul.

- ***April 17, 2009***: Expert discovery closed.

- ***June 9, 2009***: Dr. Watanabe passed away.

- ***December 31, 2009***: Judge Cavanaugh rendered a decision on cross-motions for summary judgment. Judge Cavanaugh rejects Lilly's proffered post-filing test data as legally pertinent to the question of utility.

- ***January 13, 2010***: Despite defeating Defendants' motion for summary judgment on utility/enablement, Lilly moves for reconsideration of the Court's rejection of its test data that was not submitted to the PTO.

FDA. See 21 U.S.C. § 355. As discussed herein, Dr. Paul's testimony would apparently purport to address Lilly's submission of its IND (*i.e.*, IND 46,806) to the FDA in this case.

- ***February 23, 2010***: Lilly's motion for reconsideration is denied.

- ***February 24, 2010***: This Court entered an Order scheduling trial for May 18, 2010.

- ***March 29, 2010***: The parties agreed to an April 5, 2010 deadline for the final exchange of trial witness lists.

- ***April 5, 2010***: Plaintiff formally identifies Dr. Paul for the first time. Lilly claims that he will be called as a fact witness at trial.

- ***April 6, 2010***: Plaintiff served its Statement Regarding Lay Opinion Testimony, claiming that Dr. Paul will testify, along with six other witnesses, about "the invention in suit, its background and development, acclaim and long-felt but unmet need for this invention, and how the invention is made and used."

- ***April 19, 2010*:** The final pre-trial conference is held. The issue of Dr. Paul's testimony is discussed at length.

- ***April 26, 2010:*** Plaintiff's motion *in limine* is filed, including the proffer from Dr. Paul.

- ***April 30, 2010***: Defendants' opposition to the motion *in limine* is filed.

- ***May 3, 2010***: The Court conducts a telephone conference on the outstanding motion and schedules oral argument, which is held on May 5, 2010.

C. Dr. Paul's Proposed Testimony

Lilly has claimed that Dr. Paul is a substitute witness for the deceased Dr. Watanabe and that he would testify to the same issues at trial. (Pl.'s Br. 1.) In order to determine whether Dr. Paul was sufficiently disclosed in depositions as Lilly claims, it is necessary to review Lilly's disclosure of Dr. Watanabe's knowledge, its tardy formal disclosure of Dr. Paul's knowledge, and its proffer of Dr. Paul's testimony.

In its supplemental disclosures, Lilly identified Dr. Watanabe as a person with knowledge regarding: "Certain aspects of the development of Strattera®." (Bogad Decl., Ex. E.) In Lilly's disclosure of Dr. Paul, they identified him as one 7 witnesses who may:

> Address the invention in suit, its background and development, acclaim and long felt-but unmet need for this invention, and how the invention was made and used.

(Bogad Decl., Exs. J-K.)

In addition, in its more detailed proffer, Lilly states that Dr. Paul would testify on various subjects, including:

- the steps Lilly took to develop atomoxetine.
- the various steps Lilly takes internally when it believes a chemical compound is useful in treating a disease. This would include the submission of an investigational new drug application ("IND").
- how Lilly would proceed if it believed that a drug was proving safe and effective during clinical trials.
- that atomoxetine went through Phase II and Phase III process for treatment of ADHD in children and adults under Dr. Paul's management.
- his experience operating under the framework of federal regulations and the other ethical obligations attendant to human clinical research.
- various medical ethical principles and guidelines.
- his opinion that Dr. Heiligenstein (co-inventor) is a "devoted and passionate child psychiatrist whose primary focus was helping children get the best possible treatment," and that Dr. Tollefson (co-inventor) is "an insightful drug developer and a scientist with excellent credibility before the FDA regarding the merits of the drug.

(*E.g.*, Certification of M. Andrew Holtman, Esq., at Ex. 1.)

Defendants argue that Dr. Paul's proffered testimony exceeds any Dr. Watanabe gave at his

deposition or could give at trial. Defendants claim that Dr. Paul's testimony, to the extent it discusses steps within Lilly to develop and gain approval of atomoxetine, is actually meant to focus on the IND about which Lilly previously said it had no knowledge.[4]

D Lilly Did Not Adequately Disclose Dr. Paul Under Rule 26

Lilly concedes that it did not disclose Dr. Paul in its initial disclosures or responses to discovery requests. Lilly also concedes that it did not supplement its disclosures or discovery requests and did not formally identify Dr. Paul as an individual with relevant knowledge and a potential witness until April 5, 2010, during joint preparation of the final pretrial order. Nevertheless, Lilly contends formal disclosure of Dr. Paul was not necessary because Dr. Paul's general existence and knowledge was "otherwise made known" during the course of fact depositions in this case.

For example, on October 1, 2008, prior to the close of fact discovery, Defendants deposed Dr. Watanabe, Dr. Paul's predecessor as head of Lilly's research and development of neuroscience

---

[4] Lilly's brief on a related *in limine* motion provides support for Defendants' argument and appears to allege a new and previously undisclosed theory about which Dr. Paul would testify:

> The existence of the MGH protocol, the IND [46,806], the FDA approval of the IND, and the existence MGH IRB approval to do the experiment were all disclosed in discovery. The significance of those events to the alleged non-enablement defense here flows directly from the regulatory limitations imposed on the conduct of human drug testing. Every professional responsible for drug research is aware of these limitations and requirements. Dr. Watanabe of Lilly, had he lived, could have so testified from personal experience. *So can Dr. Paul in his stead*.

(Lilly's Brief in Opposition to Defendants' Motion *in limine* to Exclude Evidence Relating to IND 46,806, dated May 3, 2010; CM/ECF No. 606) (emphasis added).

drugs. Lilly claims that repeated references to Dr. Paul during this deposition (as well as others) satisfies its disclosure obligations under Rule 26. The following are excerpts from Dr. Watanabe's deposition:

> ***Q***: Okay. How was it structured?
> ***A***: Okay. Lilly Research Laboratories was structured in different therapeutic areas.
> ***Q***: Okay.
> ***A***: And one of them was neuroscience. And the person responsible for neuroscience reported to me.
> ***Q***: And who was that?
> ***A***: That was Steven Paul
>
> * * *
>
> ***Q***: You have a specific recollection of having expressed your skepticism to Dr. Paul? Is that something you say, yes, I remember that conversation?
> ***A***: No, I can't say that.
> ***Q***: Okay. Same for Dr. Tollefson?
> ***A***: Correct. But let me just elaborate a bit here. I used to meet with Dr. Paul about once a week when we were both in town since he was one of my direct reports, we'd have maybe a one-hour one-on-one. And he would update me on a number of things, progress in certain projects, issues that were developing. We would talk about them. And then we would talk some about science, and I'm assuming, I'm vaguely recalling that in one of those conversations he probably mentioned the hypothesis and the possibility of doing a study, and that in the course of that conversation I'm pretty sure I would have told him, you know, I doubt if it would work. It might be worth studying, but I doubt if it would work. And this is the normal type of conversation that occurs in the leaders of science.
>
> * * *
>
> ***Q***: Would you agree, though, that this document was authored by Dr. Paul?
> ***A***: Uh-huh, it looks like it.
> ***Q***: You mentioned in your testimony earlier that – that you believed that Dr. Paul might have been one of two people that brought the idea or the hypothesis to you about testing tomoxetine to treat ADHD; is that correct?
> ***A***: Early on, probably the individual that introduced me to the concept initially early on. So that would have been perhaps the first part

of '95. It was either Dr. Paul or Dr. Tullefson.

(August M. Watanabe, M.D., Dep., Attached to Certification of M. Andrew Holtman, at 26:4-17; 27:11-14; 28:10-19; 58:3-25; 162:4-167:17.)

In addition to Dr. Wantabe's deposition, Dr. Paul's name also was also mentioned during the depositions of three other witnesses: John H. Heligenstein, M.D. (co-inventor of the drug in-suit); Dr. Biederman (a third-party clinician who conducted Lilly's phase II trial of atomoxetine); and Thomas J. Spencer, M.D. (a physician at Massachusetts General Hospital who conducted early clinical trials of atomoxetine).

Lilly now contends that this deposition testimony placed Defendants on notice that Dr. Paul was an individual with knowledge and a potential witness, alleviating the need for a more formal supplemental disclosure and satisfying its obligations under Rule 26(e). The Court disagrees.

Dr. Paul was vaguely identified during certain depositions. Tens or hundreds of other names were also referenced in depositions and in the extensive fact discovery process permitted in this case. Perhaps Defendants should have considered deposing Dr. Paul. However, it is Lilly's burden to disclose its fact witnesses, to clearly and candidly answer the specific discovery requests propounded, and to scrupulously update its disclosures. At a minimum, Lilly should have clearly identified persons with knowledge, the scope of knowledge, and the witnesses it intended to use to support its claims or defenses. See Fed. R. Civ. P. 26(a), (e). It did not do so. A supposed disclosure in a deposition "*must be clear and unambiguous*"—as to witness's existence and a description of his or her knowledge— in order to equate with a proper, formal disclosure. Pfizer v. Teva, No. 04-754, 2006 WL 2938723, at *3 (D.N.J. Oct. 13, 2006). If the supposed disclosure requires inferences as to the person's relevance and knowledge, the disclosure is not sufficient. See

id. The deposition testimony cited by Lilly demonstrates that Defendants were not given notice that Dr. Paul had the type of information that Lilly now seeks to have Dr. Paul testify to at trial. Although Dr. Paul's general existence may have come out in depositions, it was certainly not a disclosure that Dr. Paul would be a trial witness -- especially when coupled with Lilly's failure to list him as a witness in response to direct interrogatory questions on the subject. More importantly, the *type* and *scope* of testimony that Dr. Paul is now seeking to provide at trial was never disclosed, nor could it be inferred from the random deposition references.

Defendants should not be charged with knowledge of the type of testimony Dr. Paul proposes based on passing references to Dr. Paul in the depositions of other fact witnesses. Sporadic mentions in depositions are not a substitute for certified responses to discovery and do not satisfy Lilly's discovery obligations. Thus, the Court concludes that Lilly failed to timely disclose Dr. Paul.[5]

E. Application of Rule 37 Factors to Lilly's Non-Disclosure

Having concluded that Dr. Paul was not adequately disclosed, the Court will consider the relevant factors to determine whether he should be excluded from testifying at trial for this reason.

1. Prejudice or Surprise

There is some of each. Dr. Paul could have been identified much earlier; he was not named until about a month before trial in a 3 ½ year old case. Dr. Watanabe died 10 months ago (in June 2009), and there is no explanation for delaying until April 5, 2010, to formally identify Dr. Paul as

[5] Reliance on chance "disclosure" of witnesses or documents should especially not be tolerated in a complex patent case. The parties have had liberal discovery. Countless documents have been exchanged and many depositions taken. It is unfair to charge a party with detailed knowledge of every individual mentioned in documents and depositions in a case like this. Prudence and fairness warrant formal disclosure and supplementation in most instances. Discovery of witnesses should not depend on the reading of tea leaves. Parties should frequently check and re-check their discovery disclosures and responses to ensure accuracy and fairness in advance of trial. Failure to do so will risk exclusion.

his replacement. The eleventh hour disclosure prejudices Defendants. At the very least, Defendants have been distracted with this motion practice and have had to spend time to deal with this new witness and new theory when they could be preparing for trial. Equally troubling is that due to Lilly's conflicting statements, the true subject of Dr. Paul's putative testimony is still not clear. If Dr. Paul's testimony is permitted (and Lilly somehow overcomes what appear to be significant evidentiary obstacles to the testimony) Defendants will have to scramble to rebut Dr. Paul.

2. Ability to Cure Prejudice

The prejudice to Defendants is curable. To eliminate any surprise as to Dr. Paul's knowledge, Lilly must make Dr. Paul available for a deposition immediately. The deposition should minimize the prejudice and surprise. See, e.g., Merisant Co. v. McNeil Nutritionals, Inc., 242 F.R.D. 303, 308 (E.D. Pa. 2007) (denying, without prejudice, motion *in limine* to exclude witness who was not identified in disclosures or discovery with only one month prior to the trial date on condition witness would appear for prompt deposition).

Since Lilly caused the problem, it should pay all costs of the deposition. This shall include paying the fees for one lawyer for each Defendant to attend and take the deposition at an arbitrary rate of $400 per hour. (It shall not include costs for Defendants' counsel's preparation for the deposition.) Such an award of alternative monetary sanctions is expressly contemplated by Rule 37 and is appropriate to ensure Defendants do not incur additional costs as a result of Lilly's non-disclosure. See, e.g., Fitz, Inc. v. Ralph Wilson Plastics, Co., 174 F.R.D. 587, 591 (D.N.J. 1997) (in lieu of excluding non-disclosed witness, "plaintiffs shall be required to compensate the defendants for the legal fees and costs involved in . . . leveling the playing field . . . Specifically, the plaintiffs shall reimburse the defendants for any attorneys' fees and costs incurred in deposing the [non-

disclosed witness]").

Apart from surprise, much of the claims of prejudice are based on evidentiary and substantive objections to Dr. Paul's expected testimony. The vagueness and inconsistency of Lilly's descriptions of Dr. Paul's testimony has aggravated the situation. Of course, evidentiary and substantive questions are the sole province of the trial judge.[6] Still, this Court strongly believes that the following general conditions on Dr. Paul's testimony are necessary to alleviate any prejudice to Defendants:

1. Dr. Paul's testimony should be strictly limited to the letter of his proffer.

2. Defendants should be permitted to respond to Dr. Paul and present appropriate rebuttal witness, if necessary.

3. Subject to Judge Cavanaugh's approval, Dr. Paul should not be permitted to offer expert (or lay opinion) testimony.[7] Needless to say, there was no compliance with Rule 26's expert disclosure requirements. Lilly has represented that it is not offering Dr. Paul as an expert; Defendants argue his testimony will ultimately constitute expert opinion.

3. Disruption of Orderly Procedures at Trial

The late disclosure of Dr. Paul will not be permitted to disrupt the proceedings at trial. The trial will not be adjourned due to the late disclosure.

---

[6] Nothing in this Opinion should be interpreted to impinge on Judge Cavanaugh's total control over all aspects of the trial.

[7] Dr. Paul's proffered lay opinion testimony appears to bear on scientific or otherwise specialized information that is not the proper subject of fact testimony. See McCrary v. N.J. Transit Rail Operations, No. 05-88, 2008 WL 2885872, at *3 (D.N.J. July 23, 2008) ("The Third Circuit and other courts have noted the global preclusion of any kind of lay opinion on specialized or technical subjects." (citing Estate of Edward W. Knoster v. Ford Motor Co., 200 Fed. Appx. 106, 111 & n.3 (3d Cir. 2006)).

4. Bad Faith

The Court does not find a sufficient record has been made to support a finding of bad faith. Bad faith is most often shown through failure provide or disclose information despite repeated requests to do so. See, e.g., In re Mercedes- Benz Antitrust Litig., 225 F.R.D. 498, 507 (D.N.J. 2005). A charitable, yet plausible, explanation for the disclosure failures is that Lilly has belatedly attempted to construct a response to what it (perhaps unreasonably) deemed an unanticipated ruling on summary judgment. This does not rise to the level of bad faith.

5. Summary

The addition of Dr. Paul in the days immediately before trial is precisely the type of surprise that the Federal Rules were designed to prevent. The prejudice to the Defendants is genuine but curable. A timely deposition, with all associated costs borne by Lilly, should address much of the problem. The Court has adopted this approach because it will likely result in decision of this important case on the merits, rather than Lilly's discovery failures. Many of the evidentiary issues implicated by Dr. Paul's proffer are relatively straightforward and will likely be resolved by other pending *in limine* motions.

CONCLUSION

For the above stated reasons, and for those set forth on the record on May 5, 2010, and subject to the conditions described herein, Lilly's motion to permit Dr. Paul to testify at trial is **granted**. An appropriate Order implementing this Opinion will be entered.

s/Mark Falk
MARK FALK
United States Magistrate Judge

Dated: May 7, 2010

cc: Clerk of the Court
Honorable Dennis M. Cavanaugh, U.S.D.J.
All Counsel of Record (via ECF)
File